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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/813,829 03/06/97 HOGAN

B 16016.0005

EXAMINER

HM22/0229

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ART UNIT

PAPER NUMBER

1633

12

DATE MAILED:

02/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/813,829

Applicant(s)

Hogan, B. L. M.

Examiner

Deborah Clark

Group Art Unit

1633

☒ Responsive to communication(s) filed on Jan 10, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-4 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Response to Amendment

1. Applicant's amendment and response to the previous office action has been received, 01/10/00, paper no. 10. The amendment to claim 4, line 5 has not been entered because the words to be deleted are not on line 5 of claim 4. Applicants may have intended to delete the words from line 4 of claim 4. Applicants will need to re-submit this amendment.
2. Claims 1-4 remain pending.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. The previously made rejection under 35 USC 112, 1st paragraph is withdrawn in view of applicant's amendment. It is noted that non-murine pluripotent cells that can be cultured on feeder layers and give rise to embryoid bodies are known in the art.
5. Claims 1-4 stand rejected under 35 USC 112, 2nd paragraph.
6. Claims 1-3 as amended remain indefinite. As amended the cells are required to have the characteristics of a cell derived from a particular outlined process. It is not clear what these

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characteristics are and whether all or only one characteristic must be shared. As stated it is not clear whether applicants mean that all characteristics are necessary. Previously the claims recited that "all essential characteristics" were required. This phrase was held to be indefinite as it was not clear which characteristics were considered essential. As amended, the claims remain unclear because no specific characteristics have been outlined to define the claimed cells other than those recited in parts A and B. If the cells are only defined by the process from which they are derived, then this process must be a required limitation in the claim. Otherwise, one of skill in the art is not reasonably apprised as to the meets and bounds of the claimed invention.

7. Claim 4 stands rejected under 35 USC 112, 2nd paragraph for reasons of record. The claim continues to recite "essential characteristics" it is not clear which characteristics are deemed essential. Therefore, the skilled artisan is not apprised as to the scope of the claimed invention.

Terminal Disclaimer

8. The terminal disclaimer filed on 01/10/00 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5,453,357 has been reviewed and is accepted. The terminal disclaimer has been recorded.

9. The terminal disclaimer filed on 03/29/99 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5,690,926 has been reviewed and is accepted. The terminal disclaimer has been recorded.

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Priority

10. It is maintained that the claimed invention is not granted priority to the filing of 07/958,562. Applicant's argument has been considered, but is not deemed persuasive.

The basis for the obvious type double patenting rejection was due to the fact that the claims were co-extensive. Therefore, that rejection was proper.

The disclosure of 07/958,562 is considered insufficient under 35 USC 112, 1st paragraph over the pending claims herein because the pending claims herein are directed exclusively to non-murine pluripotent cells. There is no disclosure in the specification of 07/958,562 which enables non-murine pluripotent cells. Even though the method may have been later demonstrated as successful for isolating non-murine pluripotent cells, the claims are directed to products not methods. Therefore, the priority is granted only to 03/25/94 which is the filing date of application # 08/217,921 which matured to US Patent 5,690,926.

Claim Rejections - 35 USC § 102

11. Claims 1-3 stand rejected over Wheeler for reasons of record. Applicants argue that the priority of this application should be 10/08/92 and hence Wheeler, filed 05/14/93 is not prior art. This argument is not persuasive for the same reason as addressed above under the heading priority.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Pera et al.

Pera et al. discloses a putative human EC cell line. EC cells can be cultured on feeder layers for 20 passages and are known to form embryoid bodies. It is presumed that the cells share certain characteristics with the cells made by the process as outlined. Therefore, the claims are anticipated.

14. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Notarianni et al.

Notarianni et al. disclose pig embryonic pluripotent cells which were cultured on feeder layers and formed embryoid bodies (see pages 52 and 54). Therefore, the cells share characteristics with cells prepared by the outlined process. The claims are therefore anticipated.

Conclusion

15. No claim is allowed.

16. The signature of the group director indicates his concurrence with these rejections.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**


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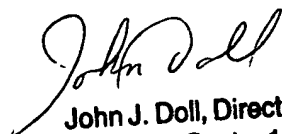
MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Clark whose telephone number is (703) 305-4051. The examiner can normally be reached on Mondays-Fridays from 7:10 a.m. EST to 3:40 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


DEBORAH J. CLARK
PATENT EXAMINER


John J. Doll, Director
Technology Center 1600